UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SHAFIGHEH KOUBLANI,

Plaintiff,

- against -

COCHLEAR LIMITED and COCHLEAR AMERICAS,

Defendants.

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MEMORANDUM AND ORDER

2:20-cv-1741 (DRH) (AYS)

APPEARANCES

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HURLEY, Senior District Judge:

INTRODUCTION

Plaintiff Shafigheh Koublani ("Plaintiff") brings this action against Defendants Cochlear Limited and Cochlear Americas Corporation ("CAM," and together with Cochlear Limited, "Defendants") alleging the following causes of action under New York state law: (1) strict products liability, (2) negligence, (3) breach of warranty, and (4) failure to warn. This matter concerns alleged defects in Defendants' Nucleus

Implant Bandage and Splint Kit for MRI (the "MRI Kit"), which is utilized to stabilize magnetic components of cochlear implant hearing devices during magnetic resonance imaging ("MRI") procedures. Presently before the Court is Defendant CAM's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). [DE 22].[1] While Plaintiff's claims are not preempted by federal law, Plaintiff has failed to state a claim upon which relief may be granted. For that reason, CAM's motion is GRANTED.

BACKGROUND

To facilitate the reader's understanding of this matter, the Court begins with an overview of the Food and Drug Administration's ("FDA") regulatory scheme for medical devices before setting forth the facts alleged in the Complaint.

A. FDA Approval Process

The FDA regulates the "safety and effectiveness" of medical devices pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 360c et seq. Every covered "medical device" fits into one of three classifications, which determines the level of FDA oversight: Class I (the least), Class II, or Class III (the most). *Id.* § 360c(a); *see id.* § 321(h)(1) (defining "medical device").

Class III is "the default category for new (that is, post-1976) medical devices." *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 83–84 (D.C. Cir. 2014) (Kavanaugh, J.) (detailing the FDA classification scheme); *see* 21 U.S.C. § 360c(f)(1) ("Any device intended for human use . . . is classified [as] class III unless . . ."). Class III devices

[1] Defendant Cochlear Limited has not been served with process, has not appeared in the case, and thus does not join in CAM's motion. (*See* Def. Mem. at 2).

must endure the FDA's premarket approval ("PMA"[2]) process, a "rigorous regime" in which the FDA spends 1,200 hours per device on average assessing:

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling.

Riegel v. Medtronic, Inc., 552 U.S. 312, 317–18, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008) (quoting 21 U.S.C. § 360e(c)(1)). If, after review, the FDA has "reasonable assurance" of the device's safety and effectiveness, it may enter the market. 21 U.S.C. § 360e(d).

Manufacturers of a PMA device may not make changes "affect[ing] [its] safety or effectiveness" without first obtaining a "supplemental PMA." *Id.* § 360e(d)(5)(A)(i); 21 C.F.R. § 814.39(a). The FDA evaluates "application[s] for supplemental premarket approval . . . under largely the same criteria as an initial application," except that the FDA requires only enough information to review the proposed modifications. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(5); 21 C.F.R. § 814.39(c)).

A device avoids PMA review if (a) the FDA, upon *de novo* review, determines it meets the Class I or II statutory definitions, 21 U.S.C. §§ 360c(a)(1)(A)–(B), or (b) it is "substantially equivalent" to a pre-existing classified device, *id.* §§ 360c(f)(1)–(3), (i)(1)(A). Per statute, Class I devices present "no unreasonable risk of illness or injury" and are regulated by "general controls." *Id.* § 360c(a)(1)(A). Class II is

[2] "PMA" means either "premarket approval" or "premarket approved" depending on context.

comprised of devices ineligible for Class I status "because the general controls by themselves are insufficient to provide reasonable assurance of the[ir] safety and effectiveness" but "for which there is sufficient information to establish special controls to provide such assurance." *Id.* § 360c(a)(1)(B).

A device is "substantially equivalent" to a pre-existing classified device—that is, a predicate Class I, II, or III device—if it has "the same intended use" and either "the same technological characteristics" or the same safety and effectiveness. *Id.* §§ 360c(f)(1)–(3), (i)(1)(A). The FDA's review for "substantial equivalence," the premarket notification "§ 510(k) process," is named after the statute's previous location. *Riegel*, 552 U.S. at 317; *see* 21 U.S.C. § 360(k). On average, the § 510 process takes the FDA twenty hours per device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996).

Though "[t]he § 510(k) notification process is by no means comparable to the PMA process," *id.* at 478–79, it is the means by which "[m]ost new Class III devices enter the market." *Riegel*, 552 U.S. at 317. To be clear, "§ 510(k) is 'focused on *equivalence*, not safety,'" and PMA "is focused on safety, not equivalence." *Id.* at 323 (emphasis in original) (internal citations omitted) (quoting *Lohr*, 518 U.S. at 493). Devices "enter[ing] the market through § 510(k) have 'never been formally reviewed under the [Medical Device Amendments] for safety or efficacy," whereas premarket approval is granted "only after [the FDA] determines that a device offers a reasonable assurance of safety and effectiveness.'" *Id.* (internal citations omitted) (quoting *Lohr*, 518 U.S. at 493).

B. CAM's PMA and Supplemental PMAs

Cochlear Limited, an Australian corporation, designs and manufactures cochlear implant hearing aid devices, which it distributes across the United States through its American subsidiary CAM, a Delaware corporation with a Colorado principal place of business. (Compl. ¶¶ 10–11, 13 [DE 18]; Def. Mem. at 3 n.3 [DE 22-1]). In June 25, 1998, CAM obtained PMA for its "Nucleus 24 Cochlear Implant System," a device "intended to restore a level of auditory sensation to adults and children via electrical stimulation of the auditory nerve." (FDA Premarket Approval No. P970051).[3] CAM has subsequently supplemented this implant system's PMA for its newer and related devices. Of note is the FDA's supplemental PMA on June 15, 2015, which approved the CAM's "Nucleus CI522 Cochlear Implant System," referred herein as the "CI522." (FDA Supplement No. S126[4] ("S126 Supp. PMA"), Ex. B to Decl. of Lauren S. Colton ("Colton Decl.")).

The CI522 is not directly in issue, and it suffices to know that it is a surgically implanted electronic hearing aid device comprised of internal (*i.e.*, surgically implanted) and external components held together by a magnet. (Compl. ¶¶ 19–21; Def. Mem. at 3). As it is ill-advised to bring magnets (and metals, generally) into MRI machines, CI522 users must take precautions prior to pursuing such treatment.

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[3] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051. All cited webpages herein are last accessed as of the date of this Memorandum and Order: June 23, 2021.

[4] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S126. Unless otherwise noted, specific FDA Supplemental PMAs cited by the Court are supplemental "to Premarket Approval No. 970051."

(Compl. ¶¶ 22, 28). "For this reason, [Cochlear Limited] designed the CI522 Device so that the magnet could be surgically removed by the patient's healthcare provider prior to undergoing an MRI procedure if desired." (Def. Mem. at 4; *see* Compl. ¶ 22).

A CI522 accessory—the MRI Kit—is in issue. The MRI Kit offers a "less invasive option" to the "surgical[] remov[al of] the magnet in advance" of MRI scans. (Def. Mem. at 4; Compl. ¶¶ 22, 24–25). It is a "flat plastic splint" to be placed "against the skin over the magnet site and secured with an elasticized compression bandage and surgical tape." (Def. Mem. at 4–5; Compl. ¶ 29). The MRI Kit provides protection in MRI scans up to 1.5 Tesla in strength. (Compl. ¶¶ 25, 27; Def. Mem. at 4; *see Tesla*, Oxford English Dictionary (3d ed. 2018) (a "unit of magnetic flux density")).

The Complaint does not mention the MRI Kit's medical device classification. Plaintiff contends CAM never obtained PMA for the MRI Kit. (Pl. Opp. at 9–11 [DE 22-7]). CAM asserts the opposite: that the FDA granted the MRI Kit supplemental PMA on July 8, 2016. (*See* FDA Supplement No. S137 ["S137 Supp. PMA" or "Supplemental PMA No. S137"],[5] Ex. A to Colton Decl.). Supplemental PMA No. S137's "approval order statement" reads:

> Approval requested for (1) a change in indications to allow MRI of implant recipients at 1.5T with the implant magnet in place for . . . CI522 . . . provided that a Cochlear-supplied MRI kit is used; (2) a change in indications to allow MRI of implant recipients at 3.0T with the implant magnet removed for . . . CI522 . . . ; and (3) consolidation of MRI-related labeling into a single document that provides appropriate instructions for the following Cochlear-manufactured implants: . . . CI522 . . . .

[5] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S137.

(*Id.* (ellipses remove six additional hearing aid devices irrelevant to this action)). To avoid any potential misunderstanding: the FDA's use of "MRI kit" (*n.b.*, lowercase "k") does not necessarily correspond to the Court's use of "MRI Kit" (capital "K" and a shorthand for the "Nucleus Implant Bandage and Splint Kit for MRI").

C. Plaintiff's Injury and Procedural History

Plaintiff, a New York citizen who is hard of hearing, had a CI522 implanted on March 14, 2017. (Compl. ¶ 18). Roughly a year later, on February 14, 2018, Plaintiff went for an MRI scan. (*Id.* ¶ 23). After being apprised of her two options relating to the CI522's magnet, she opted for the MRI Kit in lieu of surgery. (*Id.* ¶¶ 22–23, 26–27, 30–31). Yet during her procedure the magnet dislodged under her skin, causing her "severe painful personal injuries which are permanent in nature." (*Id.* ¶¶ 32, 40). Plaintiff had the dislodged magnet surgically removed and replaced on April 17, 2018. (*Id.* ¶ 38).

CAM, "over time," became aware of "inconsistencies in [the MRI Kit's] use by medical imaging professionals" as well as MRI Kit "post-market complaints" and "adverse event data." (*Id.* ¶¶ 35–36 (internal quotation marks omitted)). CAM recalled the MRI Kit, ceasing its distribution on January 6, 2020. (*Id.* ¶¶ 34–36).

Plaintiff brought suit in New York State Supreme Court, Nassau County on March 3, 2020 and served CAM on March 10. [DE 1-2]. On April 8, 2020, CAM removed to federal court on the basis of diversity jurisdiction. [DE 1]. She asserts four causes of action under New York state law: (1) strict products liability,

(2) negligence, (3) breach of warranty, and (4) failure to warn. (Compl. ¶¶ 42–70). CAM moved to dismiss on September 18, 2020. (*See* Def. Mem.).

LEGAL STANDARD

In deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court should "draw all reasonable inferences in Plaintiff['s] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted). The plausibility standard is guided by two principles. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)); *accord Harris v. Mills*, 572 F.3d 66, 71–72 (2d Cir. 2009).

First, the principle that a court must accept all allegations as true is inapplicable to legal conclusions. Thus, "threadbare recitals of the elements of a cause of action supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Although "legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 679. A plaintiff must provide facts sufficient to allow each named defendant to have a fair understanding of what the plaintiff is complaining about and to know whether there is a legal basis for recovery. *See Twombly*, 550 U.S. at 555.

Second, only complaints that state a "plausible claim for relief" can survive a motion to dismiss. *Iqbal,* 556 U.S. at 679. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference

that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but asks for more than a sheer possibility that defendant acted unlawfully. Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line' between possibility and plausibility of 'entitlement to relief.'" *Id.* at 678 (quoting *Twombly*, 550 U.S. at 556-57) (internal citations omitted); *see In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007). Determining whether a complaint plausibly states a claim for relief is "a context specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679; *accord Harris*, 572 F.3d at 72.

DISCUSSION

CAM moves to dismiss on two bases: (i) federal preemption of state law claims triggered by the MRI Kit's PMA, and (ii) failure to state a claim upon which relief can be granted. Before addressing each point, the Court begins by analyzing whether it may consider the parties' exhibits to the motion papers.

In considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a court is generally limited to the complaint and documents attached thereto. *See* Fed. R. Civ. P. 12(d); *Nakahata v. N.Y.-Presbyterian Healthcare Sys., Inc.*, 723 F.3d 192, 202 (2d Cir. 2013). A court "'may also consider matters of which judicial notice may be taken.'" *Apotex Inc. v. Acorda Therapeutics, Inc.* 823 F.3d 51, 60 (2d Cir. 2016) (quoting *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008)); *see Bristol v. Nassau County*, 2016 WL 2760339, at *4 (E.D.N.Y. May 12, 2016) ("On a motion to dismiss, consideration is limited to the factual allegations

in plaintiff's amended complaint, which are accepted as true, to documents attached to the complaint as an exhibit or incorporated in it by reference, to matters of which judicial notice may be taken, or to documents either in plaintiff's possession or of which plaintiff had knowledge and relied on in bringing suit." (internal quotation marks omitted)).

The parties each rely on public FDA records, including FDA guidance and PMAs on its website, and do not dispute the Court's ability to take judicial notice thereof. Def. Mem. at 2 n.1; *see* Pl. Opp. at 9–10, 12. Precedent supports the Court doing so. *E.g.*, *Apotex Inc*, 823 F.3d at 60 ("Although this case partially arises on a motion to dismiss, we may properly take judicial notice of [FDA guidance] (without converting Acorda's motion to dismiss into a motion for summary judgment) because the [g]uidance is publicly available and its accuracy cannot reasonably be questioned."); *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 134 n.4 (E.D.N.Y. 2018) ("District courts may take judicial notice of public records of the FDA on a motion to dismiss."); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 401 n.2 (S.D.N.Y. 2013) ("For the purpose of resolving the present motion [to dismiss], the Court takes judicial notice of public records contained on the FDA website."); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) ("The Court takes judicial notice of [the FDA's premarket approval], based on FDA public records available" on its website.). Therefore, the Court properly considers these materials on CAM's motion.

I. Preemption

The Medical Device Amendments prohibit (with limited exceptions) the states from imposing requirements "different from, or in addition to" federal "requirement[s] . . . relate[d] to the safety or effectiveness" of "a device intended for any human use" covered under 21 U.S.C. Chapter 9. 21 U.S.C. § 360k; *Riegel*, 552 U.S. at 316. "[R]eference to a State's 'requirements' includes its common-law duties," like the "general tort duties of care" underlying "negligence, strict-liability, and implied-warranty claims." *Riegel*, 552 U.S. at 324, 327–29. In *Riegel*, the Supreme Court held that such state claims are preempted if they "challeng[e] the safety and effectiveness of a medical device given premarket approval by the" FDA. *Id.* at 315, 330. Preemption does not apply, however, to state common law claims imposing requirements "parallel" to those under federal law, *Lohr*, 518 U.S. at 495; *Otis-Wisher v. Medtronic, Inc.*, 616 Fed. App'x 433, 434 (2d Cir. 2015) (summary opinion) (quoting *Riegel*, 552 U.S. at 330), though Plaintiff does not construe her claims as such, *see* Pl. Opp. at 16–18.

The preemption analysis proceeds in two steps. First, the Court determines whether the FDA "has established requirements applicable to" the device in question. *Riegel*, 552 U.S. at 321–22 (internal quotation marks omitted). If the MRI Kit was subjected to, and survived, the "rigorous" federal safety PMA review, the first step is satisfied. *Id.* at 317–18, 322–23; *Lohr*, 518 U.S. at 477–78. But if it was "subject to much lower levels of review . . . [that] d[id] not impose specific requirements on devices," then the Court does not move on to the second step. *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 331 n.1 (S.D.N.Y. 2010) (citing 21 U.S.C. § 360c(a)(1)(A)–(B));

e.g., *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 469 (D. Mass. 2012) ("[C]laims involving a device that received premarket approval satisfy the first condition of the test for preemption while claims involving a device that received § 510(k) approval do not."). Provided Plaintiff has cleared the first hurdle, the second step asks the Court to discern whether Plaintiff's "common-law claims are based upon New York requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321–22 (internal quotation marks omitted).

Here, the crux of the preemption issue here concerns the first step. The Complaint is silent as to the level of FDA review performed on the MRI Kit. To the extent descriptions of the MRI Kit in the Complaint hint at a level of review, those allegations include: (i) the MRI Kit was "specifically designed and sold by Defendants to protect [hearing] implant recipients . . . from the dangers associated with undergoing an MRI procedure," (ii) Defendants "specifically represented" that individuals with the CI522 can "safely" undergo MRI "scans at 1.5 Tesla" when "using the MRI Kit," and (iii) the MRI Kit "comprise[s] of a head bandage and rigid splints." Compl. ¶¶ 22, 25, 29 (internal quotation marks omitted).

Plaintiff contends the MRI Kit was "not the subject of" the FDA's PMA review for Supplemental PMA No. S137 and was exempt from the PMA process altogether. Pl. Opp. at 2–3, 7–8. Plaintiff asserts the MRI Kit "remains [] unvetted" and her causes of action based thereon evade preemption because the first step in the analysis is not satisfied. *Id.* CAM disagrees, arguing that Supplemental PMA No. S137

"make[s] clear that the MRI Kit was approved pursuant to the PMA process" and, if not, the MRI Kit is nonetheless an "'accessory' to the PMA-approved" CI522, such that the MRI Kit inherits the CI522's PMA for purposes of preemption. Def. Mem. at 17–19.

The Court first analyzes whether Supplemental PMA No. S137 concerned the MRI Kit and then whether the MRI Kit obtained PMA status as an "accessory" to the CI522. *Cf. Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012) ("We conclude that the determination of whether the Shell was subject to the PMA process is a question of law.").

A. Supplemental PMA No. S137

FDA regulations require healthcare device manufacturers to "submit a PMA supplement for review and approval . . . before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA." 21 C.F.R. § 814.39(a). Changes of this type include, but are not limited to, "[n]ew indications for use of the device" and "[c]hanges in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." *Id.* §§ 814.39(a)(1), (6).

Supplemental PMA No. S137 reflects CAM's requested approval for "a change in indications to allow MRI of implant recipients at 1.5 [Tesla] with the implant magnet in place for" the CI522 "provided that a Cochlear-supplied MRI kit is used." S137 Supp. PMA. The Supplemental PMA No. S137 does not name the MRI Kit at bar (the Nucleus Implant Bandage and Splint Kit for MRI) nor identify any

"Cochlear-supplied MRI kit[s]." *See id.* At this "early, pre-discovery stage," the Court is not comfortable inferring the FDA's use of "MRI kit" to connote the specific MRI Kit at issue. *See Kubicki ex rel. Kubicki v. Medtronic* ("*Kubicki*"), 2013 WL 1739580, at *5 (D.D.C. Mar. 21, 2013).

The FDA's nonspecific phrasing raises questions, and any answers justifying dismissal call for CAM-favorable inferences impermissible at this juncture. For example, how many types of Cochlear-supplied MRI kits are there? The FDA's usage of "*a* Cochlear-supplied MRI kit" could imply more than one. If more than one, did the FDA review each and every type of "Cochlear-supplied MRI kit"? Or did it review only a sample set, such as those developed after the FDA approved the seven hearing implant devices identified in Supplemental PMA S137? All these questions boil down to: How do we know the MRI Kit at issue here was among the "Cochlear-suppled MRI kit[s]" reviewed by the FDA without CAM telling us so? The Plaintiff-favorable inferences drawn from the allegations and judicially-noticed public FDA records do not answer these questions. The uncertainty counsels against dismissing Plaintiff's case on this basis. *See Kubicki*, 2013 WL 1739580, at *5 ("[T]he Court harbors serious doubt about the validity of Plaintiffs' argument regarding . . . PMA approv[al and] Class III status. Nevertheless, the Court need not, and on the incomplete factual record before it, shall not resolve the question at this early, pre-discovery stage of the litigation."); *Kavalir v. Medtronic, Inc.*, 2008 WL 4087950, at *4 (N.D. Ill. Aug. 27, 2008) ("[T]he FDA internet pages attached to Medtronic's brief do not provide a

sufficient basis for the Court to determine, at this stage of the proceeding . . . what specific form or forms of Medtronic's ICDs received premarket approval.").

There is a plausible argument that the MRI Kit did not undergo FDA PMA review. When granting supplemental PMA to CAM accessories of the Nucleus 24 Cochlear Implant System—*i.e.*, the original device granted PMA No. P970051 on June 25, 1998—the FDA uses very clear and direct language. The FDA expressly states "approval for [device]" in its Approval Order Statements. *E.g.*, FDA Supplement No. S091 ("approval for the aqua accessory for the Nucleus Cochlear Implant System" (capitalization omitted)); FDA Supplement No. S096 ("approval for the Nucleus 6 Cochlear Implant system, a new suite of external accessories" (capitalization omitted)); FDA Supplement No. S182 ("[a]pproval for new accessories . . . of the Nucleus 7 system."); FDA Supplement No. S183 ("[a]pproval for . . . two accessories (Nucleus Non-Magnetic Cassette and Nucleus Replacement Magnet Cassette)"); FDA Supplement No. S193 ("[a]pproval for the Kanso 2 Sound Processor and associated accessories").[6] No inference is necessary to understand that the FDA approved those accessory devices.

But Supplemental PMA No. S137 does not use this clear and direct language. It does not mention the MRI Kit at issue, its approval, nor approval for *any* device.

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[6] Each cited supplemental PMA can be accessed at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S091;
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S096;
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S182;
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S183;
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S193.

In place of "approval for [device]," the FDA noted a "change in indications." *See generally* 21 C.F.R. § 814.39(a)(1) (requiring supplemental PMAs for "new indications for use of the device"). Inferring that the FDA in Supplemental PMA No. S137 nevertheless approved the MRI Kit is akin to construing the facts in CAM's favor, which the Court will not do on CAM's Rule 12(b)(6) motion.

To be clear, the MRI Kit is not the device undergoing a "*change* in indications" because nothing suggests the FDA's previous awareness of the MRI Kit. *See* Def. Mem. at 4. It was the CI522 that necessitated the "change," as a key feature had become no longer necessary: the CI522 was "*designed* . . . so that the magnet could be surgically removed by the patient's healthcare provider prior to undergoing an MRI procedure." Def. Mem. at 4 (emphasis added); *see* Compl. ¶¶ 22, 24–26; Def. Reply at 2 [DE 22-12]; *see also* S126 Supp. PMA (granted on June 15, 2015). The MRI Kit obviates the surgery altogether and renders this CI522 feature obsolete.

It may very well be true that CAM's Supplemental PMA No. S137 application—a "confidential," "not publicly available" document unpresented to the Court—evidences the MRI Kit's PMA review. *See* Def. Reply at 2 n.3. But nonmovant-friendly plausible inferences drawn from the materials considered suggest otherwise. And, even if CAM is correct, persuasive authority leads the Court to question the application's relevance to the issue. *E.g.*, *Duggan*, 840 F. Supp. 2d at 472 ("Whether a product is FDA-approved is determined by the language in the approval letter, not by the application documents submitted to it for review."); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 655 (S.D. Tex. 2010) ("What was submitted in

the FDA application has little bearing on this Court's assessment of what was ultimately approved.").

Therefore, the Court cannot say the FDA performed a PMA review of the MRI Kit in granting Supplemental PMA No. S137.

B. Accessory to a PMA Parent Device

Under the Federal Food, Drug, and Cosmetic Act, Congress defined the term "device" as "including any component, part, or accessory." 21 U.S.C. § 321(h)(1). Yet it left "accessory" undefined, and the term remained undefined until the FDA issued guidance thereon in December 2017. FDA, Medical Device Accessories – Describing Accessories and Classification Pathways (2017) ("FDA Accessory Guidance"). "Accessory," that is, had no formal definition at the time CAM supposedly presented the MRI Kit to the FDA.[7] CAM nevertheless reads the "device" definition to automatically bestow PMA status onto the MRI Kit because it is an accessory to a device previously granted PMA status: the CI522. Def. Mem. at 19–20; Def. Reply at 3. Plaintiff's counter is twofold: the MRI Kit is not an accessory to the CI522, and even if it was, "[t]here is no FDA rule or regulation, nor any case that extends the PMA obtained for one [PMA] device to an accessory that has not, itself, undergone review and approval under the FDA's PMA process." Pl. Opp. at 11–13.

As a preliminary matter, earlier FDA Guidance is unhelpful to the Court's inquiry. The "Convenience Kits Interim Regulatory Guidance" from 1997 "does not

[7] CAM applied for Supplemental PMA No. S137 on November 23, 2015, which the FDA granted on July 8, 2016. The FDA published its guidance December 20, 2017.

operate to bind FDA or the public," and even if it did, simply exempts "generic" "MRI Disposable Kit[s]" "consisting of components that have been cleared through the 510(k) process." FDA, Convenience Kits Interim Regulatory Guidance (1997), https://www.fda.gov/media/72720/download. Nothing in the way Plaintiff describes the MRI fits neatly into this formulation. Defendants "specifically designed" the MRI Kit for their implants and there is no mention of components nor level of FDA review. *See* Compl. ¶¶ 22, 29.

Based on the arguments presented to, and materials before the Court, the MRI Kit is an "accessory" to the CI522. Accessories "supplement" another object, both according to the term's plain meaning and current regulatory definition. *Accessory*, Oxford English Dictionary (3d ed. 2011) ("A subordinate or auxiliary thing; an adjunct; an accompaniment."); *Accompaniment*, Oxford English Dictionary (3d ed. 2011) ("Something which accompanies, supplements, or complements something else."); FDA Accessory Guidance at 5 (defining "accessory" as "a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices"). Plaintiff pleads the MRI Kit was "specifically designed and sold by Defendants to protect implant recipients, such as Plaintiff, from the dangers associated with undergoing an MRI procedure with the Magnet in place." Compl. ¶ 22. Recall that CI522 users would, without the MRI Kit, require surgery before MRI procedures. CI522 users do not *need* the MRI Kit; it simply offers an alternative to—viz. "supplements"—the way in which they would otherwise live with the CI522. Clearly, the MRI Kit is an accessory.

An isolated review of the statutory definition of "device" tends to support CAM's position on PMA status. *See* 21 U.S.C. § 321(h)(1) ("The term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, *including* any component, part, or *accessory* . . . ." (emphasis added)). But the Court hesitates to find the definition, standing alone, dispositive where, as here, the "accessory" arrived after its parent device's PMA. The FDA granted supplementary PMA to the CI522 on June 25, 2015. S126 Supp. PMA. Five months later, on November 23, 2015, CAM filed its Supplemental PMA No. S137 application, which CAM asserts included the MRI Kit. S137 Supp. PMA.

Few courts, if any, have analyzed this issue – namely, whether "accessories" of PMA Class III parent devices are themselves PMA Class III devices. The parties' dispute over *Troutman v. Curtis*—"the single case . . . where accessories . . . are mentioned as having PMA approval based on being introduced as an accessory" to PMA device, Pl. Opp. at 15—offers little guidance because the issue was "uncontroverted" and not "challenged on appeal," *Troutman*, 143 P.3d 74, 77–78, 36 Kan. App. 633 (Kan. Ct. App. 2006). Further investigation is required.

CAM analogizes the issue to nonbinding authority extending PMA status to a PMA device's individual "components." Def. Mem. at 19 & n.17. For good reason, too, as the term "component" appears alongside "accessory" within the "device" definition. 21 U.S.C. § 321(h)(1). But the analogy is too imperfect to persuade.

First, CAM's cited cases concern components present in the very device granted PMA by the FDA, at the time of the FDA's review. *See, e.g.*, *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1003 (S.D. Ohio 2016) ("Premarket approval extends to all components of an approved device, even when a physician uses the components separately."); *Hawkins v. Medtronic*, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) ("The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself."); *Lewkut*, 724 F. Supp. 2d at 656 ("[T]his Court cannot see the logic in holding that the ceramic components of the Trident System were PMA-approved for use with the acetabular shell, but that that acetabular shell itself was not PMA approved. An acetabular shell being used in conjunction with the identified ceramic components is precisely the device that was approved via PMA."); *see also Kubicki*, 293 F. Supp. 3d at 174–75 (citing *Duggan*, 840 F. Supp. 2d at 469 (D. Mass. 2012) and *Bentzley v. Medtronic*, 827 F. Supp. 2d 443, 450–51 (E.D. Pa. 2011)). By all accounts, however, the MRI Kit did not exist at the time of the CI522's PMA. Def. Mem. at 4, 8; Pl. Opp. at 10.

Second, the FDA requires a manufacturer changing components in a PMA device to apply for a Supplemental PMA. 21 C.F.R. § 814.39(a)(6) ("[C]hanges for which an applicant shall submit a PMA supplement include, but are not limited to the following types of changes if they affect the safety or effectiveness of the device, . . . [c]hanges in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.").

CAM itself has done so for new components in its PMA hearing aid devices. *E.g.*, FDA Supplement No. S143.[8] So, the FDA does not automatically extend PMA status to new (later-implemented) components in a device, justifying the Court's hesitation to do so for a device's later-developed accessories.

Third, the FDA's Approval Order Statements for Supplemental PMAs approving new components use clear and direct language just as they do for new accessories. *Id.* ("Approval for a new . . . external component of" two hearing implant devices); FDA Supplement No. S140 ("Approval for the optional acoustic component" enabling access to "low frequency sounds"); FDA Supplement No. S088 ("Approval for a modified version of the approved CP800 Series coil to accommodate [a] magnet . . . higher than the strengths currently available." (capitalization omitted)).[9] Indeed, courts have noted the absence of this clear and direct language as a decisive factor in assessing, at the motion to dismiss stage, whether or not the FDA granted PMA to a new component. Consider *Kavalir v. Medtronic, Inc.*:

> The Court agrees that the FDA internet pages attached to Medtronic's brief do not provide a sufficient basis for the Court to determine, at this stage of the proceeding, that Plaintiff's state-law claims are preempted under *Riegel*. The pages do not on their face make clear what specific form or forms of Medtronic's ICDs received premarket approval and whether those are the same ICDs as those implanted in Plaintiff in 2000 and 2005.

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8 *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S143.

9 *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S140; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S088.

2008 WL 4087950, at *4; *see also Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298, at *4 (D.N.J. Jan. 15, 2013) ("The [*Kavalir*] court was worried that 'none of the documents attached . . . refer to the . . . lead wires used to implant the ICDs in [p]laintiff, the part [p]laintiff contends caused her injuries' . . . [and] that the [FDA website links] 'did not make clear what specific form or forms' of the ICD leads had received premarket approval. In contrast, [defendant's] lead wire is the only one at issue, and is specifically identified by the FDA's public records as having received its own premarket approval . . . ." (first two ellipses in original) (internal citations omitted)); *Lewkut*, 724 F. Supp. 2d at 655 n.2 ("[T]he public documents examined in [*Kavalir*] were insufficient . . . [because] none of the pages . . . identified the components of the medical device that were named in the plaintiff's complaint . . . [and] the pages did not sufficiently demonstrate that the components named in the complaint had received premarket approval." (internal citation omitted)). Carrying the analogy back to the accessory at hand, we know the FDA failed to use this clear and direct language in Supplemental PMA No. S137, which suggests it did not receive PMA. *See* S137 Supp. PMA; *see supra* Discussion Section I.A.

CAM asserts it is "not plausible that the FDA would approve a change in indication to allow an implantable medical device with magnetic components to remain in place during MRI procedures only where a specific accessory provided by the device manufacturer is used, without approving and imposing requirements on that accessory." Def. Reply at 2. Discovery may prove the truth of CAM's contention. But it is too early to say.

Based on the arguments presented and materials considered, the Court cannot find the MRI Kit—a subsequently-developed "accessory" to a PMA device—receives PMA simply by association with the CI522. *Cf. Brackin v. Medtronic, Inc.*, 2017 WL 5957204, at *5 (W.D. Tenn. Sept. 14, 2017) ("At this stage in the proceedings, and after briefing by both parties, the Court is unable to conclusively determine whether [plaintiff's] entire insulin delivery system, some, or none of its component parts have received premarket approval. That being the case, the Court must deny Defendants' motion to dismiss, given Defendants' burden on this issue."). Altogether, then, the preemption analysis stalls at its first step and the Court declines to grant CAM's motion to dismiss on that basis.

II. Failure to State a Claim

Plaintiff asserts four causes of action: (1) strict products liability due to design and manufacturing defects, (2) negligent design and manufacture, (3) breach of express and implied warranty, and (4) failure to warn. Compl. ¶¶ 42–70; Pl. Opp. at 20, 22–23. In this diversity action, New York state law applies to each claim. *E.g.*, Def. Mem. at 13; Pl. Opp. at 22–23, 25; *see also McCarthy v. Olin Corp.*, 119 F.3d 148 (2d Cir. 1997).

A. Strict Products Liability

Plaintiff asserts strict products liability based upon both a (1) design defect and (2) a manufacturing defect. Compl. ¶¶ 42–51; Pl. Opp. at 22–23. Under New York law, each such cause of action "rest[s] on the principle that the manufacturer is in a superior position to know when its product is suitably designed and safely made

for its intended purpose." *Fasolas v. Bobcat of New York, Inc.*, 33 N.Y.3d 421, 429, 128 N.E.3d 627 (N.Y. 2019).

1. Design Defect

Defectively designed products, "at the time [they] leave[] the seller's hands," are those in a condition "not reasonably contemplated by the ultimate consumer" and "unreasonably dangerous for [their] intended use." *Scarangella v. Thomas Built Buses, Inc.*, 93 N.Y.2d 655, 659, 717 N.E.2d 679 (N.Y. 1999) (internal quotation marks omitted). Liability follows where a product's "utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 107, 450 N.E.2d 204 (N.Y. 1983). Plaintiff must plead: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing Plaintiff's injury." *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 888 (E.D.N.Y. 2018), *adhered to on reconsideration*, 2019 WL 1118052 (E.D.N.Y. Mar. 11, 2019); *Barban v. Rheem Textile Sys., Inc.*, 2005 WL 387660, at *8 (E.D.N.Y. Feb. 11, 2005), *aff'd*, 147 Fed. App'x 222 (2d Cir. 2005); *see also Voss*, 59 N.Y.2d at 107; *Codling v. Paglia*, 32 N.Y.2d 330, 342, 298 N.E.2d 622 (N.Y. 1973); *De Matteo v. Big V Supermarkets Inc.*, 204 A.D.2d 932, 933, 611 N.Y.S.2d 970 (N.Y. App. Div., 3d Dep't 1994).

Even assuming a defect existed at the time the MRI Kit left Defendants' hands, *see infra* Discussion Section II.A.2.b and II.C.2, Plaintiff's Complaint runs afoul of a design defect claim's second element: no allegations suggest a feasible, safer

alternative design. Courts applying New York state law have held the absence of such allegations sufficient to grant a motion to dismiss strict liability design defect claims. *E.g.*, *S.F. v. Archer Daniels Midland Co.*, 594 Fed. App'x 11, 12 (2d Cir. 2014) (summary opinion) ("S.F.'s claims for . . . strict products liability based in design defects fail because she did not allege a safer alternative design for high fructose corn syrup."); *McCarthy*, 119 F.3d at 155 (dismissing design defect strict liability cause of action after applying New York law's "risk/utility test analysis" whose "purpose . . . is to determine whether the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design"); *Kennedy v. Covidien, LP*, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019) ("Although a plaintiff need not possess specialized scientific or technical knowledge at the pleading stage, courts have routinely dismissed strict products liability claims premised on a design defect where the plaintiff has failed to plead that it was feasible to design the product in a safer manner."); *Lancaster Silo & Block Co. v. N. Propane Gas Co.*, 75 A.D.2d 55, 62, 427 N.Y.S.2d 1009 (N.Y. App. Div., 4th Dep't 1980) ("In a design defect case the court is concerned with the balancing of the alternative designs available against the existing risk while taking into account the cost of the proposed alternative."); *Joline v. City of New York*, 2 Misc. 3d 1006(A), 784 N.Y.S.2d 921 (N.Y. Sup. Ct., Queens Cnty. 2004) ("In order to establish a prima facie case of strict products liability based on a defectively designed product, it is well established that a plaintiff must plead and prove that there was a feasible design alternative that would have made the product

safer."), *aff'd in part, appeal dismissed in part*, 32 A.D.3d 492, 820 N.Y.S.2d 635 (N.Y. App. Div., 2d Dep't 2006).

Plaintiff contends the pleadings are at too "early" a stage to demand allegations identifying "the existence of feasible alternative design." Pl. Opp. at 23. To Plaintiff, such allegations entail "technical, scientific knowledge" of the MRI Kit's "inner workings" uncalled for by *Iqbal* and *Twombly* and properly addressed through discovery and expert opinion. *Id.* Her case in support, however—*Ohuche v. Merck & Co.*, 2011 WL 2682133, at *2 (S.D.N.Y. July 7, 2011)—is distinguishable. As noted in *Kennedy v. Covidien, LP*, the *Ohuche* Court analyzed a pro se plaintiff's design defect claim concurrently with "a failure to warn claim" – the latter of which "requires no showing of a feasible alternative design as a requisite element." *Kennedy*, 2019 WL 1429979, at *3 & n.9. In this light, "[t]he particular circumstances in *Ohuche* cannot be read to undermine the general requirement that an alternative design must be pleaded, even if it is not fully developed at the pleading stage." *Id.* Plaintiff also relies on *Cowan v. Costco Wholesale Corp.*, Pl. Opp. at 23, but the complaint there "identifie[d] six feasible alternative" designs. *Cowan*, 2017 WL 59080, at *2 (E.D.N.Y. Jan. 5, 2017).

Accordingly, her strict products liability design defect claim fails.

2. Manufacturing Defect

"A manufacturing defect claim is premised on the relevant product being defective because it was not manufactured as designed," *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012); *see McArdle v. Navistar Int'l Corp.*, 293 A.D.2d

931, 932, 742 N.Y.S.2d 146 (N.Y. App. Div., 3d Dep't 2002), obliging a plaintiff to allege "that the particular product administered to her had a defect as compared to other samples of that product," *Goldin v. Smith & Nephew, Inc.*, 2013 WL 1759575, at *2 (S.D.N.Y. Apr. 24, 2013) (internal quotation marks and alterations omitted); *see Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 258, 662 N.E.2d 730 (N.Y. 1995) ("[I]n strict products liability cases involving manufacturing defects, the harm arises from the product's failure to perform in the intended manner due to some flaw in the fabrication process."). A plaintiff must therefore plead "that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *See Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quoting *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 129, 417 N.E.2d 545 (N.Y. 1981)). "[A] manufacturing defect claim is properly dismissed if a plaintiff has not alleged 'that the particular [device in her case] had a defect as compared to' other samples of that [device]." *Reed*, 839 F. Supp. 2d at 577 (quoting *Lewis v. Abbott Labs.*, 2009 WL 2231701, at *2 (S.D.N.Y. July 24, 2009)).

Plaintiff's claim here fails because only untethered conjecture permits the Court to infer Plaintiff's MRI Kit had a manufacturing defect. She states, "at the time" Defendants "manufacture[d]" the MRI Kit, it "was not reasonably safe and fit for the purposes intended" and "failed to meet . . . [the] manufacturing requirements to ensure that it conformed to defined use, needs, intended purpose and uses." Compl.

¶¶ 43–45. These allegations amount to a "[t]hreadbare recital[] of the elements of a [manufacturing defect] cause of action" warned against by the *Iqbal* Court. *See* 556 U.S. at 678. They do not meet the plausibility standard.

The Second Circuit affirmed dismissal of an analogous complaint on this basis. In *Rodman v. Stryker Sales Corporation*, the plaintiff pleaded "that his [hip replacement] implant was manufactured 'in an improper workmanship-like manner'" because it "'did not meet certain specifications . . . for tensile bond strength and crystallinity.'" 604 Fed. App'x 81, 82 (2d Cir. 2015) (summary opinion) (ellipses in original) (quoting Rodman's complaint), *aff'g* 2014 WL 5002095 (S.D.N.Y. Oct. 7, 2014). These allegations failed to "identif[y] how this problem rendered the product defective, whether it affected his individual hip replacement, or how it caused his alleged injuries," and were therefore insufficient. *Id.*; *see also Surdo v. Stamina Prod., Inc.*, 2015 WL 5918318, at *5 (E.D.N.Y. Oct. 9, 2015) ("[S]tating that the product was 'carelessly, negligently, and defectively designed, manufactured [and] produced[,]' . . . does not allege an error in the manufacturing process—it only states that there was one.").

More specifically, without alleging the "specific defect in the [MRI Kit] as used [by Plaintiff]," there is no factual basis to infer that Plaintiff's MRI Kit differs from a properly manufactured MRI Kit. *See Dunham v. Covidien, LP*, 2020 WL 5995102, at *4 (S.D.N.Y. Oct. 9, 2020) (dismissing manufacturing defect allegations that product "was defective in its manufacture," "deviated from manufacturing standards," and "failed to perform in its intended manner due to a flaw in the manufacturing

process"); *e.g.*, *Tears v. Bos. Sci. Corp.*, 344 F. Supp. 3d 500, 511 (S.D.N.Y. 2018) ("Tears' manufacturing defect claim fails because he fails to plead facts alleging that the Greenfield Filter with which he was implanted is defective as compared to other Greenfield Filters."); *Cowan*, 2017 WL 59080, at *4; *Goldin*, 2013 WL 1759575, at *3; *Perazone v. Sears, Roebuck & Co.*, 128 A.D.2d 15, 19, 515 N.Y.S.2d 908 (N.Y. App. Div., 3d Dep't 1987) ("While plaintiff's complaints alleged that there was a manufacturing defect, he offered no proof that, regardless of the safety of the design of the tractor, there was any impropriety in the manufacture of this particular tractor.").

Plaintiff attempts to evade pleading a "specific error in the manufacturing process" and "a defect compared to other samples of that device" by insisting it is "unduly burdensome to expect Plaintiff to have specific knowledge about Defendants' manufacturing process at this early stage of the case." Pl. Opp. at 22–23. This position overstates the pleading requirements because such expertise is not necessary. Plaintiff simply needs to allege more than "the device is defective because it did not perform properly." *Bertini v. Smith & Nephew, Inc.*, 2013 WL 6332684, at *4 (E.D.N.Y. July 15, 2013). There must be "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" of a manufacturing defect. *Twombly,* 550 U.S. at 556; *Iqbal*, 556 U.S. at 678–79 ("[Federal Rule of Civil Procedure 8] does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.").

Even so, Plaintiff is correct that district courts within the Second Circuit have absolved certain plaintiffs of their need to plead a specific defect. Pl. Opp. at 21. These courts do so by applying one of two exceptions, neither of which applies here.

a. Exception 1: Where Pleading a Specific Defect Would Require Technical or Scientific Knowledge

First is that applied by the *Williamson v. Stryker Corporation* Court. 2013 WL 3833081, at *4 (S.D.N.Y. July 23, 2013); *see also Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 182 n.9 (N.D.N.Y. 2014). The *Williamson* Court held that pleading a "specific [manufacturing] defect" would, "[u]nder some circumstances . . . require the plaintiff to possess technical or scientific knowledge about the inner workings of the product, which would contravene the notice pleading requirement of Federal Rule of Civil Procedure 8, even under the *Iqbal–Twombly* standard." *Williamson*, 2013 WL 3833081, at *4. Such was the case in *Williamson*. *Id.* (citing *Ohuche*, 2011 WL 2682133, at *2).

The exception is narrow in application. To illustrate through example, the product in *Ohuche*, from which the *Williamson* Court draws the exception, necessitated knowledge of a particular vaccine, knowledge which "[m]ost doctors d[id] not possess" and "only those select few scientists who actually created vaccines at large pharmaceutical firms" did. 2011 WL 2682133, at *2. The MRI Kit here, by contrast, "comprise[s] of a head bandage and splints," Compl. ¶ 29; it is not complex enough to trigger the exception.

In any event, the Court declines to adopt *Williamson*'s rationale. First, the *Williamson* Court relied on an observation, first made in *Ohuche*, to say the "specific

defect" requirement comes from a decision on "a motion for summary judgment, not a motion to dismiss," and thus is inapplicable at the pleadings stage. *Williamson*, 2013 WL 383308, at *4 (citing *Ohuche*, 2011 WL 2682133 (discussing *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53 (S.D.N.Y. 2001)). The *Ohuche* Court does make the summary-judgment–motion-to-dismiss distinction. *See* 2011 WL 2682133, at *2–3. But *Ohuche* did not involve manufacturing defect claims and thus does not mention the claim's "specific defect" pleading requirement. *See id.* The *Ohuche* operative complaint did not "specifically state the particular product liability claim(s) [the plaintiff] . . . assert[ed] (design defect, manufacturing defect, failure to warn)," *id.* at *3, and the court later construed it solely "to allege a product liability claim for failure to warn," *Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 150 (S.D.N.Y. 2012).

Second, New York state courts themselves grant motions to dismiss for failure to state a manufacturing defect claim when the complaint does not identify a specific defect. By way of recent example, the *Flores v. Youm* Court dismissed, at the pleadings stage, a complaint's manufacturing defect cause of action because it was "completely devoid of any facts that may demonstrate and/or constitute the very material elements [to the cause of action] in question." 69 Misc. 3d 1216(A), at *2–3, 133 N.Y.S.3d 786 (Table) (N.Y. Sup. Ct., Bronx Cnty. 2020). "The complaint contain[ed] no facts demonstrating how the product deviated from its intended design, nor . . . identify[ing] any problems in the manufacturing process that purportedly caused the device to perform in a manner not intended." *Id.*

Third, the defining element of a manufacturing defect cause of action *is* the specific defect that separates a plaintiff's particular product from properly-manufactured products. That is to say: a plaintiff's recovery for a manufacturing defect is (in most circumstances) "mutually exclusive" with recovery for a design defect. *Astoria Energy II LLC v. HH Valves Ltd.*, 2019 WL 4120759, at *4 (E.D.N.Y. Aug. 2, 2019) (Reyes, Mag. J.) ("Because design defect claims require that the product have met all design specifications, and manufacturing defect claims require that the product have deviated from design specifications, the two are often mutually exclusive."), *report and recommendation adopted*, 2019 WL 4091417 (E.D.N.Y. Aug. 29, 2019). With a manufacturing defect claim, *one* product has a defect, but with a design defect claim, *every* product has the defect. *See McCarthy*, 119 F.3d at 154–55 ("[A] manufacturing defect . . . results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm[;] . . . a design defect . . . results when the product as designed is unreasonably dangerous for its intended use."). Allegations obscuring the "specific" defect prevent defendants from discerning whether they face manufacturing- or design-defect claims. The Court recognizes an ordinary customer will likely face difficultly in determining whether a product's defect originated in its design or in its manufacture. But rather than excuse a plaintiff from pleading a "specific" defect, the law demands that she to identify a defect *regardless* of whether they bring manufacturing or design defect claims. *Guariglia v. Procter & Gamble Co.*, 2018 WL 1335356, at *3 (E.D.N.Y. Mar. 14, 2018) ("Plaintiffs must identify a particular problem in the design of a product; generally

pleading that a product is 'defective' is insufficient."); *e.g.*, *Oden*, 330 F. Supp. 3d at 888; *Reed*, 839 F. Supp. 2d at 578 ("[E]schewing the opportunity to plead facts identifying Lybrel's design defect, the Reeds merely plead the legal conclusion that the Lybrel was defective."). A plaintiff is not asked to pinpoint the origin of the defect—*i.e.*, in the design or in the manufacture—so long as she can articulate a description of the defect.

Fourth, and finally, though either exception would suffice, the *Williamson* Court analyzed in greater depth the second exception, *see infra* Discussion Section II.B.2.b, and found it applicable too, *Williamson*, 2013 WL 3833081, at *5–6 ("[I]t is well-settled that a plaintiff may rely upon the circumstances of an accident to prove the existence of a manufacturing defect if the product did not perform as intended and the possibility of other causes has been excluded. . . . That is the case here."). The Court now turns to the second exception.

b. Exception 2: Circumstantial Evidence and the Absence of All Other Causes

"[C]ircumstantial evidence" can offset the need to "identify a specific product defect." *See Ramos v. Howard Indus., Inc.*, 10 N.Y.3d 218, 223, 885 N.E.2d 176 (N.Y. 2008); *Speller ex rel. Miller v. Sears, Roebuck & Co.*, 100 N.Y.2d 38, 41–42, 790 N.E.2d 252 (N.Y. 2003). Plaintiffs availing themselves of this exception must plead (i) "the product did not perform as intended" and (ii) the "exclu[sion of] all other causes for the product's failure that are not attributable to defendants." *Ramos*, 10 N.Y.3d at 223. The Complaint clearly meets the first prong, but no allegations intimate at the second. *E.g.*, *Krulewich v. Covidien, LP*, 2020 WL 5995103, at *3 (S.D.N.Y. Oct. 9,

2020) (dismissing manufacturing defect allegations that product "failed to perform in its intended manner due to a flaw in the manufacturing process" because they did not address "circumstantial evidence . . . exclud[ing] other causes that are not attributable to the defendant").

The Complaint does not rule out alternative causes for the failure. CAM observes that Plaintiff initially asserted, in New York state court, negligence claims against the healthcare providers performing her MRI. Def. Mem. at 9, 20 (citing *Koublani v. Doe*, Index No. 609756/18 (N.Y. Sup. Ct., Nassau Cnty.)); Def. Reply at 10; *see generally Blue Tree Hotel Inv. (Can.), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 217 (2d Cir. 2004) (stating that courts "may also look to public records, including complaints filed in state court, in deciding a motion to dismiss"). And her Complaint here quotes Defendants' motivations in recalling the MRI Kit as including "inconsistencies in its use by medical imaging professionals over time." *Id.* ¶¶ 35–36. So when the Complaint makes no allegation regarding *how* the MRI Kit was placed on her head, *i.e.*, that her MRI technician correctly fitted her with it, Plaintiff leaves open the possibility of alternative causes for the product failure. Plaintiff's sole allegation on this point reads, "On February 14, 2018, an MRI Kit was applied to Plaintiff's head prior to an MRI procedure." *See* Compl. ¶¶ 30–32. Plaintiff's allegations must address the manner in which the MRI Kit was applied to avail herself of this exception.

Plaintiff's strict products liability manufacturing defect claim is therefore dismissed.

B. Negligence

"To establish a cause of action sounding in negligence, a plaintiff must establish the existence of a duty on defendant's part to plaintiff, breach of the duty and damages." *Greenberg, Trager & Herbst, LLP v. HSBC Bank USA*, 17 N.Y.3d 565, 576, 958 N.E.2d 77 (N.Y. 2011) (citing *Akins v. Glens Falls City School Dist.*, 53 N.Y.2d 325, 333, 424 N.E.2d 531 (N.Y. 1981)); *see McCarthy*, 119 F.3d at 156 (citing *Becker v. Schwartz,* 46 N.Y.2d 401, 386 N.E.2d 807 (N.Y. 1978)). Plaintiff asserts negligence in two respects: negligent design and negligent manufacture.

"Under New York law, a Plaintiff's claim based upon an alleged design defect or manufacturing defect sounding in either negligence or strict liability are functionally equivalent and will be analyzed concurrently," in the sense that a fatal flaw in the strict liability allegations likely defeats the negligence claim as well. *Oden*, 330 F. Supp. 3d at 887; *see Kosmynka v. Polaris Indus., Inc.*, 462 F.3d 74, 86 (2d Cir. 2006) ("Both [strict products liability and negligence] entail a showing that a product defect caused the injury; but to show negligence, the plaintiff must also prove that the injury caused by the defect could have been reasonably foreseen by the manufacturer."); *S.F.*, 594 Fed. App'x at 12 ("New York courts generally consider strict products liability and negligence claims to be functionally synonymous."); *Adams v. Genie Indus., Inc.*, 14 N.Y.3d 535, 543, 929 N.E.2d 380 (N.Y. 2010) ("[W]hile plaintiff here has pleaded both strict liability and negligent design causes of action, the standards set forth in *Voss* [59 N.Y.2d 102] apply to both."); *Searle v. Suburban Propane Div. of Quantum Chem. Corp.*, 263 A.D.2d 335, 338, 700 N.Y.S.2d 588 (N.Y. App. Div., 3d Dep't 2000) ("[I]n a design defect case there is almost no difference

between a prima facie case in negligence and one in strict liability." (internal quotation marks omitted) (quoting *Lancaster Silo & Block Co.*, 75 A.D.2d at 62)).

"[E]ven if the standards did differ meaningfully, the elements of strict liability design defect would be included within the required elements for negligent design, so where a strict liability claim is dismissed so too must a negligence claim based on the same defect." *Tears*, 344 F. Supp. 3d at 509 n.2 (citing *Kosmynka*, 462 F.3d at 86).

As the Court has dismissed the strict liability design defect and manufacturing defect claims, so too must it dismiss for the same reasons their negligence counterparts, viz. that Plaintiff has not satisfactorily identified a feasible alternative design nor a basis to infer Plaintiff's MRI Kit differed from those properly manufactured.

C. Breach of Warranty

Plaintiff's third cause of action concerns breach of express and implied warranty. Compl. ¶¶ 59–63.

1. Breach of Express Warranty

A breach of express warranty claim stems from "an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to plaintiff's detriment." *Cowan*, 2017 WL 59080, at *5 (alteration and internal quotation marks removed) (quoting *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 625 (S.D.N.Y. 2012)); *Friedman v. Medtronic, Inc.*, 42 A.D.2d 185, 190, 345 N.Y.S.2d 637 (N.Y. App. Div., 2d Dep't 1973). "To state a claim for breach of express warranty under New York law, a plaintiff must

allege (1) the existence of a material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach." *Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014).

Plaintiff alleges she "reasonably relied" on "Defendant[s'] warrant[y] that Plaintiff could safely undergo an MRI procedure with her Magnet in place under skin provided the MRI Kit was used." Compl. ¶¶ 16, 61. Without the "when, where and how" leading to her reliance, however, her express warranty claim is too conclusory to pass muster under Rule 12(b)(6). *Oden*, 330 F. Supp. 3d at 895; *e.g.*, *Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 225 (W.D.N.Y. 2016) ("Plaintiff has not pleaded any facts regarding where, when, and how the alleged statements and promises regarding the Durata lead were made to him or his physicians . . . ."); *Gelber*, 788 F. Supp. 2d at 165; *Fisher v. APP Pharms., LLC*, 783 F. Supp. 2d 424, 431–32 (S.D.N.Y. 2011) (citing cases). In other words, Plaintiff must plead facts elaborating "beyond" the legal conclusion "that [she] did so" rely. *Krulewich*, 2020 WL 5995103, at *6; *e.g.*, *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286 (E.D.N.Y. 2009) ("Nowhere in her amended complaint does plaintiff allege that she relied on defendants' alleged representation that the Trident system was 'safe.' Plaintiff does not even describe how this representation was made."); *Babalola v. Crystal Chems., Inc.*, 225 A.D.2d 370, 372, 644 N.Y.S.2d 1 (N.Y. App. Div., 1st Dep't 1996) (reversing denial of motion to dismiss because, "[e]ven if we were to find that defendants had

warranted that the product was 'mild,' there was no evidence of any reliance on that representation"); *Mayen v. Tigges*, 36 Misc. 3d 1231(A), 959 N.Y.S.2d 90 (N.Y. Sup. Ct., Dutchess Cnty. 2012) (granting motion to dismiss as "plaintiffs have failed to allege the terms of any express warranty or their alleged reliance on the same"). Accordingly, the breach of express warranty claim is dismissed.

2. Breach of Implied Warranty

A breach of implied warranty can relate to a product's "merchantability" or "fitness for a particular purpose," *e.g.*, *Tears*, 344 F. Supp. 3d at 513–14, the former of which is raised here. *See* Compl. ¶¶ 59–63 ("Defendants warranted . . . that said MRI Kit was safe, merchantable, suitable and fit for the purpose for which it was intended."). The implied warranty of merchantability safeguards the consuming public's "expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners." *Denny*, 87 N.Y.2d at 259–60; *see Krulewich*, 2020 WL 5995103, at *7. It enables recovery where "the product was not minimally safe for its expected purpose—without regard to the feasibility of alternative designs or the manufacturer's 'reasonableness' in marketing it in that unsafe condition." *Denny*, 87 N.Y.2d at 259; *see Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 433–34 (2d Cir. 2013).

CAM argues, "The mere fact that Plaintiff was injured is 'insufficient to establish that the [MRI Kit] was not minimally safe for its intended purposes when it was shipped.'" Def. Mem. at 25 (quoting *Dellatacoma v. Polychem Corp.*, 2014 WL 1641467, at *2 (S.D.N.Y. Apr. 24, 2014)). That principal is certainly true on summary

judgment—*Dellatacoma*'s procedural posture—which asks a nonmovant to produce evidence to contest a movant's prima facie showing. *See* 2014 WL 1641467, at *2 ("Plaintiff has failed to proffer any evidence of a design or manufacturing defect in the pallet. He simply relies on the allegation that the pallet broke when he stood on it. The fact that one accident occurred is, however, insufficient . . . [and] Defendants are entitled as a matter of law to summary judgment dismissing Plaintiff's breach of implied warranty claim.").

To survive a motion to dismiss—the procedural posture here—a plaintiff need only plead that "a defect in the product was a substantial factor in causing the injury and . . . that the defect complained of existed at the time the product left the manufacturer or entity in the line of distribution being sued." *Guariglia*, 2018 WL 1335356, at *6 (ellipses in original) (internal quotation marks omitted) (quoting *Macaluso v. Herman Miller, Inc.*, 2005 WL 563169, at *4 (S.D.N.Y. Mar. 10, 2005)); *cf. Fritz v. White Consol. Indus., Inc.*, 306 A.D.2d 896, 897, 762 N.Y.S.2d 711 (N.Y. App. Div., 4th Dep't 2003) (quoting *Tardella v. RJR Nabisco, Inc.*, 178 A.D.2d 737, 576 N.Y.S.2d 965 (N.Y. App. Div., 3d Dep't 1991)). Plaintiff pleads the first element: The MRI Kit overheated and dislodged the CI522 magnet and therefore constitutes a substantial factor in causing Plaintiff's injury. Compl. ¶¶ 32, 38, 49. The MRI Kit is not "safe for its expected purpose" (to make MRI procedures less burdensome for hearing implant users by circumventing the need to surgically remove the implant's magnet) if an injury, otherwise foreseeable when a magnet is placed into MRI machines, still occurs. *See Guariglia*, 2018 WL 1335356, at *7.

But Plaintiff's allegations fall just short on the second element. Without alleging her technician applied the MRI correctly, the Court is left to speculate that a defect "existed at the time" the MRI Kit left CAM's hands. *See* Discussion Section II.A.2.b.

D. Failure to Warn

Plaintiff's fourth and final cause of action grounds liability in Defendants' failure to warn, which hinges on (1) a manufacturer's duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) a failure to do so proximately causing the harm.[10] Compl. ¶¶ 64–70 (alleging duty, breach, causation, and damages); Pl. Opp. at 23–24 (citing *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 Fed. App'x 8, 10 (2d Cir. 2011) (summary opinion) (reciting the elements "[t]o prevail on a claim for negligent failure to warn" and citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237, 700 N.E.2d 303 (N.Y. 1998))). A manufacturer's duty to warn extends to a product's "latent dangers" and "unintended uses," provided the foreseeability element is met. *Liriano*, 92 N.Y.2d at 237. "The duty 'extends to the original or ultimate purchasers of the product . . . and to third persons exposed to a foreseeable and unreasonable risk of harm by the failure to warn.'" *In re New York City Asbestos Litig.*, 27 N.Y.3d 765, 788–89, 59 N.E.3d 458 (N.Y. 2016) (quoting *McLaughlin v. Mine Safety Appliances Co.*, 11 N.Y.2d 62, 68, 181 N.E.2d 430 (N.Y. 1962)). "Warnings are not required if the danger is open and

[10] "Under New York law, failure to warn claims are identical under strict liability and negligence theories of recovery." *DiBartolo*, 914 F. Supp. 2d at 611 (internal quotation marks omitted).

obvious or if the plaintiff was aware of the risk." *Saladino v. Stewart & Stevenson Servs., Inc.*, 704 F. Supp. 2d 237, 247 (E.D.N.Y. 2010) (citing *Liriano*, 92 N.Y.2d at 241).

CAM faults Plaintiff for failing to "identify any specific warnings or how those warnings were inadequate." Def. Mem. at 22 (citing *Bertini*, 2013 WL 6332684, at *3–4 and *Surdo*, 2015 WL 5918318, at *5). Indeed, the Complaint equivocates on whether (a) Defendants failed to issue any warnings altogether or (b) Defendants provided warnings, which were insufficient. Compl. ¶ 46 ("[T]he MRI Kit failed to be accompanied by proper and sufficient . . . warnings concerning the use, the dangers and hazards attendant thereto."). "[A] failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how provided warnings were inadequate." *Reed*, 839 F. Supp. 2d at 575.

Plaintiff's failure-to-warn allegations, at their most specific, state that Defendants withheld the "risks and dangers associated with use of the MRI Kit." Compl. ¶¶ 46, 64–70. Second Circuit district courts have dismissed near-identical failure-to-warn claims as inadequately pleaded. *E.g.*, *Ainette v. Mkt. Basket Inc.*, 2021 WL 1022590, at *13 (S.D.N.Y. Mar. 16, 2021); *Surdo*, 2015 WL 5918318, at *5 (dismissing failure to warn of "known hazards, dangers and defects" claim). The Court agrees in their reasoning and likewise dismisses Plaintiff's failure to warn claim.

CONCLUSION

For the reasons discussed above, CAM's motion is GRANTED and Plaintiff's claims are dismissed without prejudice. Plaintiff's request for leave to amend her Complaint is GRANTED. *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991) ("It is the usual practice upon granting a motion to dismiss to allow leave to replead."). As noted herein, Plaintiff's Complaint omits certain factual allegations that may otherwise make her claims plausible. "Whether or not [she] can actually cure the deficiencies in the Complaint remains to be seen, but because the Court bases its dismissal of the Complaint primarily on Plaintiff's failure to allege non-conclusory facts in support of its claims, leave to replead is appropriate." *Goldin*, 2013 WL 1759575, at *7 (citing *Reed*, 839 F. Supp. 2d at 580). Plaintiff shall file an Amended Complaint within forty-five (45) days of this Order.

SO ORDERED.

Dated: Central Islip, New York
June 23, 2021

s/ Denis R. Hurley
Denis R. Hurley
United States District Judge